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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,362	07/24/2000	Christopher A. Bradfield	13238.00005	8301

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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	12

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DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/555,362	BRADFIELD ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-20,24,27,30-32,34-37 and 39* is/are pending in the application.

4a) Of the above claim(s) *9, 11-15, 24, 27, 30-32 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,10,16-20,35-37 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 May 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is a 371 national stage filing of PCT/US98/25314, filed November 28, 1997, which claims benefit to US provisional application 60/066,863, filed November 28, 1997.

Applicants amendment filed April 26, 2002, paper number 10, has been received and entered. Claims 7, 21-23, 25, 26, 28, 29, 33, 38 and 40-43 have been canceled. Claims 17 and 18 have been amended. Claims 1-6, 8-20, 24, 27, 30-32, 34-37 and 39 are pending.

Election/Restriction

Applicant's election of Group I, claims 1-6, 8-20, 24, 27, 30-32, 34-37 and 39, in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). In addition, Applicant's election with traverse of the species of MOP3 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that MOP4 and MOP9 should be examined together with the elected species of MOP3 because the sequences are related and represent a reasonable number of species to be contained in a single patent application. This is found persuasive in part because upon review of the specific sequences, Examiner would agree that MOP3 and MOP9 share significant homology and are homologues of one another. The species of MOP3 and MOP9 will be examined together. With respect to MOP4, it is appreciated that the protein interacts with other MOP protein(s), however this

relationship demonstrates the difference at a structural and functional level between MOP9 and the elected species, highlighting the difference among the specie of MOP disclosed. Beyond the separate search for the specific sequences disclosed and encompassed by MOP9, a search for other relevant structural and functional attributes of MOP9 would also be required. Because MOP9 is unique and distinct from other species of MOP disclosed, the election of species is maintained with respect to MOP9.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6, 8-20, 24, 27, 30-32, 34-37 and 39 are pending. Claims 9, 11-15, 24, 27, 30-32 and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10. Claims 1-6, 8, 10, 16-20, 35-37 and 39 are currently under examination as they are drawn to an isolated nucleic acid molecule of the elected species of MOP3 and MOP9.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825. 37 CFR 1.821(d) states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims, even if the sequence is also embedded in the text or the description or claims of the patent application. In the instant case, the figures contain sequences that do not have specific SEQ ID NOs associated with them neither in the figure nor the short description of the drawings in the specification.

Additionally, upon review the specification additional sequences not provided in the sequence listing have been identified. For example page 58, line 27 teaches a specific polynucleotide sequence (also see page 60, lines 1-3 for example). It is recommended that the entire specification be reviewed and each of the specific sequences requiring a sequence identifier be identified and listed in a new sequence listing in compliance with 37 C.F.R. 1.821 - 1.825.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8, 10, 16-20, 35-37 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case the broadest claims are drawn to sequences generically set forth as MOP3 and MOP9. Dependent claims set forth that the sequences share homology with SEQ ID NOs: 3 and 9, or encode the protein set forth in SEQ ID NOs: 12 and 17, however the specific nature of the homology or functional attributes of the MOP3 and MOP9 polynucleotides are not set forth in the claims. A review of the specification indicates that the specific SEQ ID NOs cloned and representing a single species of MOP3 and MOP9 have been characterized in relation to other MOP proteins, however the specific nature that is encompassed by the terms MOP3 and MOP9 is not specifically defined in the specification. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*"

Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

While the specification and the art provides adequate written description for the isolated nucleic acid sequences designated by SEQ ID NOs: 3 and 9, and a nucleic acid sequence encoding a protein comprising the amino acid sequences designated by SEQ ID NO: 12 and 17 which encodes MOP3 and MOP9 respectively, the specification fails to adequately describe other nucleic acid sequences which hybridize to these sequences that do not encode these proteins, natural mutants, allelic variants, or the gene for these terms. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998). In the instant case, the specification describes the cloning of complete cDNA sequences that were previously known in the art as EST sequences (page 33). The specification defines several unique but related nucleic acid sequences termed MOP sequence, however the specification fails to describe the relevant and specific identifying characteristics of all the nucleic acid sequences. The skilled

artisan cannot envision all the possible variant nucleic acid sequences encompassed by the claims or which hybridize but do not encode the specific SEQ ID NOs representing the encoded proteins, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Applicants attention is drawn to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein it was stated:

In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers,* 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such

genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

In the instant case, only one species of each of the polynucleotide sequences are disclosed. All the potential variations encompassed by the claims representing variants, mutants and sequences that hybridize are not taught in the specification nor the art of record. Therefore, only an isolated polynucleotide sequence consisting of the recited SEQ ID NOs taught in the specification to be MOP3 and MOP9 meet the written description provision of 35 U.S.C. §112, first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 8, 10, 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically,

Claim 1 encompass all the limitations specifically set forth in dependent claims. Claim sets forth that the encoded protein is MOP3 or MOP9, however dependent claims 5 and 6 recite

that the sequences encoding MOP are essentially the same as specific SEQ ID NOs. The metes and bounds of the claims are unclear and indefinite because what is encompassed by the terms MOP3 and MOP9 are not clearly set forth in the claim nor the specification. For example, it is unclear if a sequence nearly identical to SEQ ID NO: 3 (MOP3), but identified by another name would be considered encompassed by the claim because it is not identified as MOP3. The terms provided are not sufficient to define the metes and bounds of the product claimed. Furthermore, with respect to claims 5 and 6, it is unclear what the metes and bounds of 'substantially the same' encompasses laking any identification of what is considered 'substantial' or the 'same'. Finally, it is unclear what specific characteristics are sufficient or necessary to define MOP3 and MOP9. As acknowledged by Applicants, and as taught in the instant specification MOP3 and MOP9 share sequence homology and function, being considered homologues of each other. While each specific cloned sequence has been provided a descriptive name, it is unclear what this name/term would encompass. As discussed above, the dependent claims clearly set forth that the terms are drawn to sequences other than the specific SEQ ID NOs originally described for MOP3 and MOP9, and the metes and bounds of these names are indefinite because what is encompassed by the terms is not clearly set forth to define the terms by themselves or from one another as they represent homologues.

Claims 10 and 16 are vague and unclear in the recitation of 'natural mutant' because what one would consider 'natural' is not clearly defined. If a mutant is found it is unclear how one would determine if the mutant is a naturally occurring mutant. Further, if a mutation is

introduced into an isolated sequence it is unclear if this mutant sequence would be encompassed by the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 10, 16-20, 35-37 and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by Hogenesch *et al.* (JBC, 1997).

Hogenesch *et al.* disclose the cDNA sequence of MOP3 and describe the protein domains of the encoded protein sequence (see figures 1 and 2 for example) . Further, Hogenesch *et al.* describe the oligonucleotide sequences and vectors used to clone MOP3 (page 8582). Hogenesch *et al.* describe the use of fusion protein constructs which are transformed into cells and used in further analysis such as the two-hybrid system (see figure 5) and *in vivo* cell reporter assays (see figure 6). As taught in the instant specification, MOP3 and MOP9 share sequence homology and are considered homologues of each other. Because the breadth of the claims include sequences that are substantially the same, natural mutants, sequences that

hybridize and other variants defined functionally, the sequence and teachings for the use of MOP3 would also anticipate MOP9.

Claims 1-6, 10, 16-20, 35-37 and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by Genebank accession numbers U51627 (April 12, 1997).

Genbank U51627 discloses the cDNA and encoded protein sequence of MOP3 (as disclosed in Hogenesch *et al.*, JBC, 1997). As discussed above, the instant specification, MOP3 and MOP9 share sequence homology and are considered homologues of each other. Because the breadth of the claims include sequences that are substantially the same, natural mutants, sequences that hybridize and other variants defined functionally, the sequence and teachings for the use of MOP3 would also anticipate MOP9.

Claims 1-6, 8, 10, 16-20, 35-37 and 39 are rejected under 35 U.S.C. 102(a) as being anticipated by Ikeda *et al.* (IDS reference, February 1997).

Ikeda *et al.* disclose the cDNA sequence of BMAL1 sequence. A sequence comparison of the polynucleotide sequence disclosed by Ikeda *et al.* and the description of the protein domains of the encoded protein sequence (see figures 2 and 3) indicates that BMAL1 is highly homologous to MOP3 disclosed in the instant specification. Ikeda *et al.* describe the oligonucleotide sequences and vectors used to clone BMAL1 (page 259, starting at the top of first column). As discussed above, the instant specification, MOP3 and MOP9 share sequence

homology and are considered homologues of each other, and because the breadth of the claims the sequence and teachings for the use of MOP3 would also anticipate MOP9.

Claims 1-6, 8, 10, 16-20, 35-37 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank accession number T77200 (March 1995) or H17840 (June 29, 1995).

A sequence comparison of the polynucleotide sequence disclosed T77200 and H17840 indicates that the EST sequences are highly homologous to MOP3. As disclosed in the instant specification these sequences represent the EST clones representing MOP3 (see table on page 33). The Genbank entry indicates that the sequences were contained in vectors and maintained in host cells. Again, as discussed above, the instant specification, MOP3 and MOP9 share sequence homology and are considered homologues of each other, and because the breadth of the claims the sequence and teachings for the use of MOP3 would also anticipate MOP9.

Conclusion

No claim is allowed. The complete polynucleotide sequences of MOP 3 and MOP9 set forth as SEQ ID NOs: 3 and 9, and encoding the complete polypeptide sequences set forth as SEQ ID NOs: 12 and 18 are free of the art of record. Claims 10 and 16 recite these embodiments, however these claims include other limitations subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732. After January 12, 2004, the Examiner's telephone number will be (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. After January 12, 2004, Deborah Reynolds telephone number will be (571)272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141. After January 14, 2004, Dianiece Jacobs telephone number will be (571)272-0532.

Joseph T. Woitach